REMARKS

Applicant's counsel thanks the Examiner for her continued very careful examination of the present application. Claims 24 and 27 have been amended to overcome the Examiner's rejections under 35 USC § 112 in a manner not affecting their scope. Regarding claim 24, referring to the priority document which was originally written in the German language, the term "Laehmung nach Verletzungen/Schaedigungen nach Operationen, Fall, Schlag, vsw." was translated as "paralysis postlaesion cause alicuia mechanica." Applicant believes this to be the correct Latin-origin term for the recited disorder, however more literally translated the German phrase becomes: paralysis after injury/lesions after surgical procedures, fall, impact, etc. Applicant has now amended claim 24 to recite "paralysis following or induced by injury, lesions, surgical procedures, fall or impact," which is clearer. Also, claim 17 has been amended to limit the occurrence of the phrase "and wherein."

The Examiner has maintained her rejection of claims 1-8 and 16-27 (of which claims 1, 17 and 24 are independent) based on the previously cited references. Specifically, the Examiner's rejection is made under 35 USC § 103 on the ground the claims are allegedly obvious over Ljunggren and/or Mallasz, in further view of Stevens, McCarthy, Zimmer, Shen, Borbely et al. [Borbely], Murase et al. [Murase], Vittone, BE723594, and Iordachel et al. [Iordachel]. The Examiner has recognized that "obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." Office action (paper no. 8) at page 3.

Respectfully, and as explained below, applicant submits that the Examiner has failed to demonstrate any such motivation, either in the references themselves or in generally available knowledge of persons skilled in the art.

Regarding claim 1, this claim recites a preparation comprising sulfur, mustard seed and a cupric salt. The Examiner has recognized that neither of the main references (Ljunggren or Mallasz) discloses or suggests a composition for treating rheumatic syndromes that includes mustard seed or a cupric salt. In fact, Ljunggren discloses nothing more than a composition comprising sulfur, FeS_2 and FeS (and kaolin), and is absolutely silent as to any other ingredients, or any reason or motivation to seek or select other ingredients. Similarly, Mallasz discloses nothing more than a composition that can be applied to the skin via a carrier (such as a plaster carrier or a bandage), the composition including an "active metal ingredient" that can be in the form of metal powder, shavings, wire, etc., (see col. 2 lines 4-12, cited by the Examiner) and a quantity of a "trace" or "deficiency" element, such as sulfur. Nothing in the above-cited passage from Mallasz even remotely suggests a cupric salt, or provides any motivation for a person of ordinary skill in the art to combine the "trace" sulfur with a cupric salt. Mallasz is entirely silent as to mustard seed, or as to any reason or motivation to include mustard seed in the composition of Mallasz. Therefore, ***clearly*** the motivation to combine Ljunggren or Mallasz with

any of the other nine cited references ***cannot have come*** from these references alone.

Turning now to the nine secondary references, these references have been relied upon to supply the necessary teachings with respect to a cupric salt, mustard seed, chamomile, camphor, and potassium iodate. The following analysis discloses that the required motivation also cannot have come from any of the secondary references.

First, for the cupric salt the Examiner has relied on three secondary references, McCarthy, Zimmer and Shen, which are now discussed.

McCarthy discloses an anti-inflammatory composition of DMSO (dimethyl sulfoxide), copper sulfate, magnesium sulfate, kaolin (filler) and water. Notably, McCarthy *contains no sulfur or mustard seed*, nor does it provide any motivation or suggestion whatsoever to provide such ingredients.

With respect to Zimmer, contrary to the Examiner's argument the composition of this reference does not include coppers sulfate. Rather, *copper salycilate*, the active ingredient in the disclosed composition, can be synthesized by reacting potassium salycilate with copper sulfate to yield the copper salycilate product. Here, copper sulfate is a reactant or precursor to the active ingredient in the final composition, but is not itself disclosed as an ingredient in the composition. Again, notably, in addition to failing to disclose even copper sulfate in the finished composition, Zimmer also fails to disclose or even suggest providing the other ingredients of claim 1, mustard seed and sulfur.

Shen discloses a capsule that is prepared by grinding and capsulizing nux vomica, Semen Daturae, and calcined native copper. Just as Zimmer, Shen does not disclose a cupric salt as the Examiner has argued. Calcined native copper is not a cupric salt. Also, notably, just as in McCarthy and Zimmer above, Shen provides no motivation or suggestion to provide the other ingredients of claim 1, namely sulfur or mustard seed, in a pharmaceutical preparation for treating rheumatic syndromes.

To supply the teaching of mustard seed, the Examiner has relied on Kovacs, Li, Stevens and Gruenwald. Kovacs discloses a cream that contains a mixture of eight plant extracts obtained by ethanol/acetate extraction of the following plants: mint, white mustard seeds, wild chestnut seeds, aniseed, camilla flowers, peppermint, achillea and willow. These plant extracts are mixed with traditional cosmetic carriers to provide a cream. Notably, there is no mention of any other single ingredient, besides mustard seed, present in any of the pending claims in the present application. Nor does Kovacs provide any motivation or suggestion to provide any such ingredients. Kovacs discloses a medicinal cream comprised of various plant extracts which appears to be complete on its face.

Li discloses an externally applied powder that is also made from a vast assortment of plant extracts, namely: sichuan aconite root, wild aconite root, white mustard seed, dahurian angelica root, large-leaf gentian, notopterygium root, safflower, ledebouriella root, cinnamon twig, and mulberry twig. These ingredients are crushed and sieved and soaked in warm water prior to application to the skin.

Again, notably, no mention, motivation or suggestion with respect to any of the other claimed ingredients is found in Li.

Stevens provides a composition for imparting warmth to the feet made from powdered cayenne pepper, powdered ginger, powdered mustard and at least one powdered aromatic substance. Gruenwald merely discloses various attributes of mustard seed, and describes its native plant (Brassica Nigra). Again, notably, these two references are silent as to any other ingredient in any of the claimed combinations.

For chamomile, the Examiner has relied on Borbely and Murase. Borbely discloses a composition including alcoholic extracts of Helleborus species, one of peppermint, juniper, pine, lavender *or* Natricaria chamomilla, lanolin, cetyl-stearic alcohol, stearin, glycerol/PG, and sodium lauryl sulfate. Hence, Borbely does not even directly disclose that chamomile (Natricaria chamomilla) is or should be used in his composition, but rather lists chamomile as one of five plant-extract alternatives that can be used. In addition, and notably as above, none of the other ingredients present in any of the pending claims is found, motivated or suggested in Borbely.

Similarly, Murase discloses a cell-anchoring inhibitor comprising ten plant extracts including dried, crushed or extracted products from: Artemigiacapillaris, Euphorbia kansui, Agastache rugosa, Glechoma hederacea, Matricaria chamomila, Euphorbia lathyris, Spirodela ployrhiza, Mentha haplocalyx and Isodom japonicus. Again, notably, no disclosure, motivation or suggestion of any of the other ingredients present in any of the pending claims is found in this reference.

For camphor, the Examiner has relied on BE723594 and Vittone. BE723594 is a composition of lanolin, camphor and vaseline. Vittone is a solution in methyl alcohol of camphor, spearmint, sassafrass oil, clove oil, methyl salicylate and mustard oil. Again, notably, neither reference even remotely suggests addition or inclusion of any of the other ingredients from any pending claim in the present application.

Finally, for potassium iodate, the Examiner relies solely on Iordachel. Iordachel discloses an antiseptic composition comprising hydrolyzed collagen, metalloid iodine, potassium iodate, sodium citrate, salicylic acid, and optionally anhydrous glycerol and/or PEG400, in water. This reference, just as all those previously described, is absolutely silent as to even a single other one of the ingredients recited in any of the pending claims in the present application. Absolutely no motivation or suggestion is provided in Iordachel, either to provide sulfur, mustard seed, cupric salt, etc., into the composition of Iordachel, or to provide potassium iodate in the compositions of any of the other cited references, including the two main cited references, Ljunggren and Mallasz.

From the above discussion, it is clear that none of the references discloses or suggests the combinations necessary to sustain the rejection of the pending claims under Section 103. Not only do none of these references fairly suggest or motivate one of ordinary skill in the art to look to any of the other references to supply missing ingredients, but there is no teaching or suggestion in any reference of any shortcoming or void that can or might be fulfilled by resort to additional ingredients

from other sources.

The only remaining source that can supply the **necessary** motivation for combining any of the above references is the generally available knowledge of a person of ordinary skill in the art at the time the invention was made. First, with respect to claim 1, it is not clear how the Examiner proposes to sustain the rejection of the composition comprising sulfur, mustard seed and a cupric salt based solely on the knowledge of a person having ordinary skill in the art. As demonstrated above, the Examiner has failed to produce a single authoritative reference suggesting the combination of these ingredients **was** known or contemplated by any skilled persons, and the Examiner has also filed to establish that such combination **would have been obvious** to a skilled person based on generally available knowledge. Without admitting the truth or validity of this position, *even supposing* that sulfur, mustard seed and cupric salt were known ingredients, the Examiner has not provided any reason that a skilled person **would have made the combination**. This is because proof of this point would require two elements, both of which are utterly missing in this case:

1. evidence that a person of ordinary skill in the art would have known of these ingredients, and further would have contemplated their combination to treat rheumatic syndromes; and

2. a reasonable expectation of success.

Number 1 above is in fact **disproven** by the cited references; each reference discloses a distinct composition in its own right, each containing perhaps one of the

ingredients recited in claim 1, but none of the references demonstrate either the combination of two or more claimed ingredients, or any reason to presume or expect a person of skill in the art would have considered combining them. Number 2 above is also lacking in this case. First, each of the recited compositions in the references teaches a complete composition complete, disclosed as being effective, without more, to treat rheumatic syndromes and/or various other disorders. There can be no reasonable expectation of success for a proposed combination when the proposed combination itself is not motivated by any particular deficiency for which success could be measured.

Second, perhaps more importantly, there has been no adequate showing by the Examiner of any reasonable expectation of success for the composition recited in claim 1, or in any of the other claims. In an attempt to meet this burden, at pages 7-8 of the Office action the Examiner states (with respect to claims 17-22):

> ...at the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of adding any of the pharmaceutical preparations comprising mustard seed taught by Gruenweld, Kovacs, Li and Stevens, adding any of the pharmaceutical preparations comprising cupric salts taught by McCarthy, Zimmer and Shen, adding any of the pharmaceutical preparations comprising camomile taught by Borbely and Murase, adding any of the pharmaceutical preparations comprising camphor taught by Vittone and BE723594, and adding the pharmaceutical preparation comprising potassium iodate taught by Iordachel to the pharmaceutical preparation taught by Ljunggren and/or Mallasz to provide the claimed invention because mustard seed, cupric salts, camomile, camphor, and potassium iodate were known ingredients having the beneficial functional effect of treating rheumatic syndromes, as evidenced by the referenced teachings.

Applicant respectfully disagrees. Regarding claim 1, which recites sulfur, mustard seed and a cupric salt, the fatal flaw in the Examiner's reasoning above is that the bald combination of Ljunggren and/or Mallasz with Gruenweld, Kovacs, Li and Stevens (mustard seed), and then also with McCarthy, Zimmer and Shen (cupric salts) would provide a composition necessarily having **all of the components** of all of these references. There is absolutely no basis from these references to select *which* components from *which* reference should be combined to provide an effective composition as the one recited in claim 1. The applicant herein had the inventive insight to combine the appropriate components to provide an effective composition for the treatment of rheumatic syndromes, and that effective composition (claim 1) has not been shown by the Examiner to be obvious in view of what a person of ordinary skill in the art would have known. Certainly, there has been shown absolutely no reasonable expectation of success for selecting the three components recited in claim 1, from among, and without requiring, the tens of other ingredients from all of the suggested combined references, to provide the claimed composition. This is not to be understood to *exclude* any of these other components from the scope of claim 1, but only to point out that in claim 1 the three required elements (or their equivalents) provide an effective composition for the treatment of rheumatic syndromes, which composition is not rendered obvious even assuming the proposed combination of references.

Regarding claim 8, the Examiner's above-quoted reasoning is even more tenuous. Claim 8 recites a composition comprising particular weight percent ranges of sulfur, camomile, camphor, mustard seed, copper sulfate, potassium iodate and talc. Thus, to achieve the combination of claim 8, it is necessary to combine **all eleven** of the cited references, and to select the particular ingredients recited in claim 8 from among, and without requiring, the tens, perhaps hundred, other ingredients from all eleven references, to provide the claimed composition. Again, this is not to be understood to *exclude* any of these other components from the scope of claim 8, but to demonstrate that the recited elements of claim 8 (or their

equivalents) provide an effective composition which is not rendered obvious even assuming the proposed combination of **all eleven** references.

The Examiner has argued that the pending claim rejections are based "on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients." Office action, page 8. This proposition fails here because, as explained above, the references do not explain or provide any basis to presume which of the myriad components of their respective compositions are the "effective" components in those compositions, nor what particular effect any of those components has such that a person of ordinary skill in the art would have recognized which components to select in order to achieve the alleged "additive effect" of particular ingredients. This case is distinguishable from *In re Sussman*, cited by the Examiner, because in that case it was demonstrated that each reference disclosed specifically which were the active ingredients, and even more specifically, which active ingredient was responsible for what result. Here, no such showing has been made, and none is evident from the cited references.

Claims 17 and 24 are each method claims and have been rejected by the Examiner based on the same arguments and reasoning traversed above. Therefore, like claims 1 and 8 above, the rejections of claims 17 and 24 are believed improper as based on an improper combination of the cited references.

Accordingly, the rejections of claims 1, 8, 17 and 24 are believed to be improper as explained above, and it is respectfully submitted that each of these claims is now clearly patentable over the cited references. All other pending claims are dependent claims, and are thus also submitted as being allowable on that basis.

Therefore, all claims now being in condition for allowance, notice to that effect is respectfully requested.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 16-0820, our Order No. 33809.

Respectfully submitted,

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